

PAMELA WARREN, et al., )  
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Plaintiff, )  
)  
v. ) No. 4:10 CV 1346 DDN  
)  
HOWMEDICA OSTEONICS CORP. and, )  
STRYKER CORP., )  
)  
Defendants. )

This action is before the court on the motion of defendants Howmedica Osteonics Corporation and Stryker Corporation for reconsideration of the court's December 8, 2010 Memorandum and Order denying defendants' motion to dismiss. (Docs. 22, 23.) The parties have consented to the exercise of plenary authority by the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(c). (Doc. 16.)

On June 7, 2010, plaintiffs Pamela and David Warren commenced this action against defendant Howmedica Osteonics Corporation ("Howmedica") in the Circuit Court of St. Louis County. (Doc. 1-1 at 4.) Howmedica and Stryker Corporation<sup>1</sup> removed the action to this court under 28 U.S.C. § 1441, on the basis of federal question, diversity, and supplemental jurisdiction. (Doc. 1 at ¶¶ 10-12.)

On July 7, 2010, defendants moved to dismiss plaintiffs' complaint under Fed. R. Civ. P. 12(b)(6), arguing that plaintiffs' claims are expressly preempted under 21 U.S.C. § 360k(a), and impliedly preempted under 21 U.S.C. § 337(a). (Docs. 2, 3.) On December 8, 2010, the court issued its Memorandum and Order denying defendants' motion. (Doc. 22.)

<sup>1</sup>As previously noted, both Howmedica and Stryker Corporation will be shown as the named defendants until clarified by the parties and ordered otherwise by the court. In this Memorandum, the court refers to defendants individually or collectively as "defendants."

On December 22, 2001, defendants filed the instant motion for reconsideration, based on the Eighth Circuit's holding in In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200 (8th Cir. 2010), which had not been decided when the parties initially briefed defendants' motion to dismiss.

## **II. MOTION FOR RECONSIDERATION**

Although motions for reconsideration are not expressly provided for in the Federal Rules of Civil Procedure, Broadway v. Norris, 193 F.3d 987, 989 (8th Cir. 1999), Fed. R. Civ. P. 60(b)(6) permits the court to revisit a final judgment, order, or proceeding for "any . . . reason that justifies relief." Fed. R. Civ. P. 60(b)(6). Relief is proper under Rule 60(b)(6) only "where the exceptional circumstances have denied the moving party a full and fair opportunity to litigate his claim and have prevented the moving party from receiving adequate redress." Monsanto Co. v. E.I. Dupont de Nemours & Co., No. 4:09 CV 686 ERW, 2010 WL 3039210, at \*1 (E.D. Mo. July 30, 2010) (internal quotation omitted). Because In re Medtronic was not decided until after the parties briefed defendants' motion to dismiss, the court reconsiders defendants' motion to dismiss.

## **III. DISCUSSION**

### **A. In re Medtronic**

In In re Medtronic, the Eighth Circuit addressed the contours of express and implied preemption of state law claims arising from the malfunction of Food and Drug Administration ("FDA")-approved Class III medical devices. The court recognized the "narrow gap" through which a plaintiff's state law claim must fit to avoid express preemption under 21 U.S.C. § 360k(a), as held in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and implied preemption under 21 U.S.C. § 337(a), as held in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001):

The plaintiff must be suing for conduct that *violates* the [Food, Drug, and Cosmetic Act] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the [Food, Drug, and Cosmetic Act] (such a claim would be impliedly preempted under Buckman).

In re Medtronic, 623 F.3d at 1204 (emphasis in original).

The court then addressed the plaintiffs' claims. In their first claim, the plaintiffs alleged that Medtronic failed to adequately warn consumers of known defects and an unreasonably dangerous risk present in the device. Id. at 1205. Notably, however, the plaintiffs "did not allege that Medtronic modified or failed to include FDA-approved warnings," and instead alleged that "by reason of state law, Medtronic was required to give additional warnings." Id. The court held that these claims were preempted because they were state requirements that were "different from or in addition to" the federal requirements. Id.

Similarly, the court affirmed the dismissal of the plaintiffs' claims that Medtronic negligently continued to sell the original version of the device after the FDA approved the sale of a modified version. Id. The court explained that because the FDA did not prohibit Medtronic from selling the original version, a state requirement to the contrary would be "different from or in addition to" the federal requirements. Id.

The court also held that the plaintiffs' claims - "that Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations" - were preempted by § 337(a), because the claims were "an attempt by private parties to enforce the MDA." In re Medtronic, 623 F.3d at 1205-06.

In their design defect claims, the plaintiffs alleged that Medtronic designed the device "in a dangerous and defective condition" in contravention of the Medical Device Amendments to the Food, Drug, and Cosmetic Act. Id. at 1206. The court held that these claims were preempted by § 360k(a):

Absent concrete allegations that the product sold by Medtronic was not the product design approved in the [Pre-Market Approval ("PMA")] Supplement, these are not parallel claims. Rather, they are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k.

Id. The court reasoned that "[s]tate tort law that requires a manufacturer's [Class III device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." Id. (second alteration in original) (quoting Riegel, 552 U.S. at 325).

The court then addressed the plaintiffs' manufacturing defect claims. In these claims, the plaintiffs alleged that the device "[was] defectively manufactured because Medtronic used unreliable direct resistance spot welding to affix the device's cables to electrodes" and that "facilities or controls used by [Medtronic] in the manufacture, packing, storage, or installation of the [device] were not in conformity with the [FDA Current Good Manufacturing Practices found in the Quality System Regulations applicable to all medical devices]." In re Medtronic, 623 F.3d at 1206 (internal quotation omitted). The district court held that because the Current Good Manufacturing Practices provide only "general objectives" for all device manufacturers, dismissal was proper, as "[the plaintiffs] failed to identify any specific federal requirement in the PMA approval for the [device] that form[ed] the basis for an unpreempted parallel claim." Id.

The Eighth Circuit affirmed, but also recognized that the plaintiffs' argument - that the court imposed "an impossible pleading standard because the FDA's specific federal manufacturing requirements are set forth in the agency's PMA approval files that are accessible, without discovery, only to [the device manufacturer] and to the FDA" - "would have *considerable force* in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." Id. (emphasis added). However, because the plaintiffs argued that all of the devices had an unreasonably high risk of fracture failure (and thus all people who had an implanted device were entitled to damages) *despite* FDA authorization of the spot welding, and because the plaintiffs "specifically disclaimed the need for discovery," the plaintiffs' claims were "a frontal assault on the FDA's decision to approve a PMA Supplement," and thus were not parallel. Id. at 1207.

Regarding the plaintiffs' breach of warranty claim, the court suggested that breach of expressly warranty claims are not expressly preempted by § 360k. Id. at 1207-08. However, because the plaintiffs claim - that the device was not safe and effective, despite FDA approval of the PMA Supplement - would be contrary to the FDA's conclusion, the plaintiffs' claims were preempted by § 360k. Id. at 1208.

## B. Present Case

In the case at bar, plaintiffs raise five claims. In Count I, plaintiffs assert a strict product liability claim against defendants, as defendants were the manufacturers, distributors, and sellers of Pamela Warren's defective hip device. (Doc. 1-1 at ¶¶ 41-50.) In Count II, plaintiffs assert a negligence claim against defendants as designers, manufacturers, distributors, and sellers of Pamela Warren's defective hip device. (Id. at ¶¶ 51-60.) In Count III, plaintiffs assert a breach of express warranty of fitness for a particular purpose claim. (Id. at ¶¶ 61-69.) In Count IV, plaintiffs seek punitive damages. (Id. at ¶¶ 70-73.) In Count V, David Warren seeks damages for loss of consortium. (Id. at ¶¶ 74-77.)

Defendants argue that plaintiffs' claims are impermissibly based on violations of Current Good Manufacturing Practices, and thus must be dismissed under In re Medtronic.

Although plaintiffs allege that the Trident System implanted in Pamela Warren was not manufactured in conformity with the FDA's Current Good Manufacturing Practices,<sup>2</sup> plaintiffs also allege that defendants failed to manufacture the Trident System at issue in accordance with the FDA PMA standards for the Trident System. Specifically, plaintiffs allege:

The device at issue in this case is defective and unreasonably dangerous in that: [1] [defendants'] manufacturing processes for the device and its components did not meet or satisfy the FDA's Pre-Market Approval standards for such devices; [2] the failure of the manufacturing processes for the devices and components to meet or satisfy the FDA's Pre-Market Approval standards for such devices resulted in unreasonably dangerous manufacturing defects; and

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<sup>2</sup>Defendants contend that claims can never be based solely on allegations that the device was not manufactured in conformity with the FDA's Current Good Manufacturing Practices, and that claims must be based on allegations that the device was not manufactured in conformity with the FDA PMA requirements for the device at issue. The court need not consider the merits of this argument because, as discussed below, plaintiffs' claims are also based on allegations that defendants "violated a federal requirement specific to the FDA's PMA approval of this Class III device." In re Medtronic, 623 F.3d at 1207.

[3] [defendants] further failed to warn of the unreasonable risks created by such manufacturing defects.

[T]he acetabular hip implant device was defective and unreasonably dangerous because [defendants were] negligent and careless in the manufacturing processes for the Trident hip devices and components hereof, in that [defendants] did not meet or satisfy the FDA's Pre-Market Approval standards for such devices, and such negligence and carelessness directly caused or contributed to cause defective and unreasonably dangerous manufacturing defects, and [defendants] failed to warn of the unreasonable risks created by such defects.

As a direct and proximate result of [defendants'] violations of the . . . the Pre-Market Approval Application, . . . [Pamela Warren's] non-conforming and/or adulterated hip implants were defective and unreasonably dangerous such that the right hip implant catastrophically failed and fractured, requiring revision surgeries; [] the devices were and are subject to clicking, squeaking, grinding, or other extraordinarily noisy function and use; and further subject to poor fixation fit and function; all of which caused o[r] contributed to cause injury and damages to [Pamela Warren]."

(Doc. 1-1 at ¶¶ 37-39.)

Applying In re Medtronic, plaintiffs' claims survive preemption because they are based on "allegations that the product sold by [defendant] was not the product" approved by the FDA. In re Medtronic, 623 F.3d at 1206. As such, plaintiffs' claims are not "attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device," but rather, plaintiffs' claims allege that defendants failed to manufacture the Trident System in conformity with the FDA's PMA specifications, which resulted in a defective device whose manufacture and design were not approved by the FDA. Id. See also In re Medtronic, 592 F. Supp. 2d at 1161 n.17 ("[A]n adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption.").

Other circuits have also held that state law claims based on allegations of a manufacturer's failure to comply with device-specific FDA PMA specifications survive preemption. See Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010) ("Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they

comply with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's violation of federal law.") (emphasis in original); Carson v. Depuy Spine, Inc., 365 Fed. App'x 812, 814 (9th Cir. 2010) ("[B]ecause the product received pre-market approval from the FDA, [the plaintiff] must prove the variation in her [medical device] was from specifications approved by the FDA."). Cf. Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011) ("It is clear that all of [the plaintiff's] state products liability claims that purport to impose liability on [the manufacturer] despite [the manufacturer's] compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties that are expressly preempted."); Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001) ("[A] medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims brought with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval.").

Therefore, because plaintiffs allege that defendants "violated a federal requirement specific to the FDA's PMA approval of [the Trident

System],” plaintiffs claims survive preemption.<sup>3</sup> In re Medtronic, 623 F.3d at 1207.

### 3. Concrete Allegations

Defendants also argue that under In re Medtronic, plaintiffs must bring “concrete allegations” that the specific device at issue was not manufactured in compliance with FDA PMA specifications. In re Medtronic, 623 F.3d at 1206. However, the Eighth Circuit also recognized “the care that courts must exercise in applying Riegel’s parallel claim principle at the pleading stage, particularly to manufacturing defect claims.” Id. at 1207. Although plaintiffs have not argued that they do not yet have access to the Trident System’s PMA specifications,<sup>4</sup> the court must be mindful not to hold plaintiffs “to an impossible pleading standard.” Id.

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<sup>3</sup>Defendants also cite to Stengel v. Medtronic, No. CV 10-318-TUC-RCC, 2010 WL 4483970 (D. Ariz. Nov. 9, 2010); Cornwell v. Stryker Corp., No. 1:10-cv00066-EJL, 2010 WL 4641112 (D. Idaho Nov. 1, 2010); Cenac, et al. v. Hubbell, Civil Action No. 09-3686, 2010 WL 4174573 (E.D. La. Oct. 21, 2010); and Burgos v. Satiety, Inc., No. 10-CV-2680 (JG), 2010 WL 4907764 (E.D.N.Y. Nov. 30, 2010), in support of their argument. However, plaintiffs’ claims survive under these holdings as well because plaintiffs allege that defendants failed to manufacture the specific Trident System in accordance with the FDA PMA specifications. Stengel, 2010 WL 4483970, at \*2 (the plaintiff’s claims were preempted because they “would impose a higher duty upon [the defendant] than what was required of them during the PMA process”); Cornwell, 2010 WL 4641112, at \*3-4 (the plaintiff’s product liability claims were preempted by the MDA because “the medical device at issue in . . . was approved via the PMA process”); Cenac, 2010 WL 4174573, at \*5 (the plaintiffs’ claims that were premised on violations of Current Good Manufacturing Practices were preempted because these regulations do not “impose any specific requirements related to [the defendant’s] manufacturing process or the [specific] pump at issue”); Burgos, 2010 WL 4907764, at \*3 (to survive preemption, the plaintiff must allege “that the design, manufacture, or marketing of the [specific] device deviated in some way from the specifications approved for clinical trials by the FDA”).

<sup>4</sup>This is not to say that plaintiffs have access to these materials. See In re Medtronic, 623 F.3d at 1211 n.7 (Melloy, J., concurring in part and dissenting in part) (“Federal regulations provide that the information about a PMA applicant’s ‘manufacturing methods or processes, including quality control procedures’ generally are not available for public disclosure unless that information has been previously disclosed to the public.”) (quoting 21 C.F.R. § 814.9(h)(1)).

at 1206. See also id. at 1209-14 (Melloy, J., concurring in part and dissenting in part). Unlike the In re Medtronic plaintiffs, plaintiffs have not "specifically disclaimed the need for discovery in opposing [defendant's] motion to dismiss," nor did they make a "belated request for discovery to see if they could find [a federal requirement specific to the FDA's PMA approval of the Trident System that Medtronic may have violated]." Id. at 1207. Thus, plaintiffs are permitted to proceed to discovery to determine which particular PMA specifications defendants may have violated in manufacturing Pamela Warren's Trident System.

In sum, because plaintiffs' claims are based on allegations that defendants failed to manufacture the Trident System implanted in Pamela Warren in conformity with FDA PMA specifications, plaintiffs' claims are not preempted.

#### **IV. CONCLUSION**

For the reasons discussed above,

**IT IS HEREBY ORDERED** that motion of defendants Howmedica Osteonics Corporation and Stryker Corporation for reconsideration (Doc. 23) is sustained and upon reconsideration the motion to dismiss (Doc. 2) remains denied.

/S/ David D. Noce  
**UNITED STATES MAGISTRATE JUDGE**

Signed on March 29, 2011.